Science Board 2006

OFFICE OF WOMEN'S HEALTH (OWH)

I. INTRODUCTION

The U.S. Food and Drug Administration's Office of Women's Health (OWH) was established in 1994 by congressional mandate. OWH's budget is Congressionally mandated with occasional additional mandates and funding for the Office. OWH's mission is to:

- Protect and advance the health of women through policy, science, and outreach
- Advocate for inclusion of women in clinical trials and appropriate analysis of sex/gender

OWH performs the following core functions:

- Advises the Commissioner and other key officials on women's health issues
- Collaborates with and provides technical assistance to FDA Centers/Offices
- Develops a research agenda to identify and understand sex differences in FDA regulated products
- Monitors the inclusion of women and other demographic groups in products applications, reviews, and labels
- Translates results of research and forms partnerships for the dissemination of information to FDA stakeholders

OWH serves as a champion for women's health by:

- Ensuring that FDA functions, both regulatory and oversight, remain gender sensitive and responsive
- Working to identify and correct gender/sex disparities in drug, device and biologics testing, and regulation policy
- Monitoring progress of priority women's health initiatives within FDA
- Promoting an integrative and interactive approach regarding women's health issues across all the organizational components of the FDA
- Forming partnerships with government and non-government entities, including consumer groups, health advocates, professional organizations, and industry, to promote FDA's women's health objectives.

OWH funds research and education/outreach programs on pressing women's health issues. It utilizes a competitive peer review process for selection of the highest quality projects, with a focus on addressing particular women's health issues that have the highest regulatory impact.

The office is involved with tracking the inclusion of women in clinical studies and the detection of analyses of trial data to look specifically at sex differences in safety and efficacy. OWH has sponsored scientific workshops and conferences regarding the inclusion of women in clinical

studies and has been involved with regulations and FDA guidance documents that address this issue.

OWH works to raise awareness and provide focus throughout FDA on important women's health issues. The office has provided scientific, policy, and advocate input with questions involving the safe and effective use of numerous products including breast implants, thalidomide, postmenopausal hormone symptom therapy, contraceptive products, bone measurement devices, mammography, and much more.

OWH staff provides information on women's health issues to Congress, the media, health professionals, women's health advocates, and consumers by publishing articles in scientific/medical journals, disseminating informational materials for consumers, maintaining our website of useful women's health information, and speaking in public to audiences and constituencies interested in women's health and FDA's involvement with women's health issues.

II. CONGRESSIONAL MANDATES

	Congressional Mandate	Earmarks*	Total ($)
FY1994	"Expand and strengthen FDA's infrastructure with regard to women's health by establishing an Office of Women's Health in the Office of the Commissioner….Office will – "Work to correct **gender disparities** in FDA drug, device, biologics testing and regulation policy" – "Oversee the implementation of revised clinical trial **guidelines** with respect to representation of women" – "**Coordinate** PHS women's health policy with the PHS Office of Women's Health and other PHS agency offices of women's health as appropriate"	-	2,000,000
FY1995-2001	No change	-	-
FY2002	"…Develop an **agency-wide database** focused on women's health activities to include **demographic** data on clinical trials…"	500,000	
FY2003	No change	-	3,000,000
FY2004	"…Women's health outreach activities, including the **hormone replacement education initiative**….partner with medical professional and women's health groups, as well as other Federal agencies…"	1,425,000	3,675,000
FY2005	"…designing systems and collecting data to find the crucial differences between women and men's diagnosis, treatment, and outcomes for a given disease…research, data analysis, and outreach related to **cardiovascular disease** in women…"	1,425,000	4,000,000
FY2006	No change	-	4,000,000

*Breakdown of earmarks:
$500,000 – demographic data initiative
$500,000 – Hormone replacement education initiative
$250,000 – Cardiovascular disease – research, data analysis, and outreach
$75,000 - Hormone therapy education program continuation and expansion

IV. PERSONNEL

OWH has 14 FTEs, 2 are currently vacant; 2 additional ORISE fellows.

TITLE		AREA OF EXPERTISE
Director	Kathleen Uhl, MD*	Board certified in Family Medicine, additional fellowship training in medical research and clinical pharmacology
Special Assistant to Director	filled	Science-based project management, communications, general biological sciences
Medical Officer	filled	Board certified in OB/GYN, clinical aspects and health professions education on women's health
Administrative Officer	filled	Budget, personnel, project management
Lead Secretary	filled	Administrative support
Staff Assistant	filled	Program/ Administrative support
OUTREACH		
Program Director	filled	Consumer education strategies, partnerships, media
Health Program Coordinator	filled	Gerontology, partnership development, project management
Health Educator	filled	Health literacy education
ORISE Fellow	filled	Social science data collection, consumer information
RESEARCH & DEVELOPMENT		
Program Director	**VACANT**	
Demographics		
Supervisory Health Promotion Officer	filled	Veterinary medicine, epidemiology, risk assessment and management
Health Program Coordinator	filled	Epidemiology, biostatistics, cardiovascular disease, data management
Science		
Health Program Coordinator, Intramural	filled	Statistics, epidemiology, clinical trials methodology
Health Program Coordinator, Extramural	**VACANT**	
ORISE Fellow	filled	Nursing, clinical research, cardiac arrhythmias

3 staff are US Public Health Service Commissioned Corps Officers.

V. PROGRAM AREAS:

OWH has the following program areas:

1. Outreach Program
2. Research and Development.

The Research and Development Program is divided into:

a. Demographic Data Initiative
b. Science Program

1. OUTREACH PROGRAM

OWH Outreach Program spreads key messages to millions of women each year. This program works to identify key agency priorities regarding women's health and sex differences and to effectively deliver health messages to women around the nation. The major focus of this program is consumer information about FDA regulated products with the intent to improve health for all consumers including women. The program develops partnerships and collaborators with stakeholder organizations that facilitate outreach and consumer information dissemination. These partnerships have resulted in unprecedented dissemination of FDA/OWH materials using a variety of media venues (e.g., print, radio, television).

The program focuses on underserved and non-English speaking women. Most of the OWH literature has been translated into English and Spanish and menopausal hormonal therapy materials have been translated into almost 20 languages. Activities are diverse in scope, for example, involving grass-roots campaigns led by national organizations, panel discussions at national medical professional and women's advocacy group meetings. The Outreach Program has conducted specific informational campaigns for consumers. OWH has several ongoing campaigns including Take Time to Care, Use Medications Wisely, and menopause hormone therapy. OWH is developing campaigns related to cardiovascular disease, health fraud and safe medication use and is working on Medication Charts for consumers depicting drug information for specific classes of drugs, e.g., antidepressants, tobacco cessation products. Information is available from our website and informational fact sheets and other materials are available via the Federal Clearinghouse (FCIC) in Pueblo, CO.

OWH outreach funds FDA field staff (Public Affairs Specialists in ORA) annually with ~$100K in order to distribute OWH materials regionally. OWH also provides FDA news, alerts, and information to Congress, the press, health professionals, and women's health advocates via our extensive "contacts database". OWH has a contractor that is developing a Contacts Database to create an extensive database of groups with women's health interests (currently there are >50 categories, >6000 names/contacts). OWH has merged its list of partners with a DHHS department wide list to produce a database of partners, collaborators, and supporters in women's health of unrivaled scope and content.

These contacts can be used to create distribution lists for specific topic areas, e.g., diabetes. The database categories include:

National Organizations
Health Professional Organizations
Disease Specific Organizations (e.g., ADA)
Major Corporations
Faith-based Groups
Minority Groups
Women's Advocacy Groups

The Outreach Program has developed external partnerships that help to distribute materials developed by OHW. Partners provide approximately $11 to every FDA dollar spent for OWH outreach campaigns. Some examples of OWH partners include:

American Medical Association
American Pharmaceutical Association
Parade Magazine
Ford Motor Company
Church Women United
National Business Group on Health
National Association of Chain Drug stores
North American Menopause Society
National Lighthouse for the Blind
Kroger and other groceries
"Dear Abby"
National Conference of Mayors
Blue Cross/Blue Shield
American Diabetes and Cancer Associations
NIH, CMS, FCIC/Pueblo and HRSA

FDA's OWH has been endorsed by the AMA. Dear Abby mentioned the Take Time to Care information kits in a one of her columns and this resulted in the distribution of over 100,000 kits and over 2 million pieces of information (in first two weeks). This program has received numerous well-deserved awards and recognitions, some that are FDA and DHHS awards, but more notably are the external awards including the Pinnacle Award of the American Pharmaceutical Association and Health Care Quality Alliance (representing 97 national health organizations), Excellence in Community Partnership Development Award of the National Association of Women's Health, and GSA FCIC Consumer's Choice Award, no name just a few.

2. RESEARCH AND DEVELOPMENT

The Research and Development Program in OWH is composed of 2 distinct entities: the Demographic Initiative and the Science Program. Since the intent of this document is to educate the Science Board regarding OWH's Science Program, the Demographic Initiative will only be briefly discussed.

a. Demographic Data Initiative

In FY2002 OWH was charged with a Congressional mandate calling for an "agency-wide database focused on women's health activities." OWH's approach to this mandate was to take a systematic look at the IT infrastructure in FDA with the intent to develop a knowledge management system for FDA that could house information, data and software to support a fully electronic review environment that would be able to track inclusion of women in clinical studies. This project has been called the Demographic Information and Data Repository (DIDR). OWH has worked with the Centers in FDA to evaluate data gathering and reporting practices.

The DIDR Program is essentially an information management system that would encompass several data warehouses to include all submissions to FDA, all reviews of submissions, and all product labels. This system, or a similar one, could allow for an Agency wide information management infrastructure that would improve the ability to report demographic data (e.g., sex, race, ethnicity and age) in clinical trials and product labeling and to determine whether or not specific analyses of these demographic groups were performed. This initiative requires an integrated, automated structure and would require the creation of additional electronic warehouses, standards for electronic submission of data, standards for reviewer analysis and templates for reviews all of which can feed directly into a database that can provide the basis for demographic data analyses across studies, products, and Centers.

OWH has worked extensively with FDA's Center for Drug Evaluation and Research (CDER) to create the foundation for which to build such an IT infrastructure. OWH worked with CDER to develop standards for electronic submission of data and study protocols. OWH has also worked with CDER to create an electronic review template called a "SMART" document – allowing for implementation of Good Review Practices (GRPs) in automated fashion. This will potentially results in better consistency across reviews and, in the future, could potentially allow for a searchable and analyzable database of reviews. OWH and CDER are currently conducting an 18 month pilot of this "SMART" review template, which should end in mid-2007. In addition OWH worked with CDER with the development of a "Labeling Warehouse System" for electronic drug product labeling that, also in the future, may allow for search, query, reporting and archiving capabilities.

b. Science Program

The Office of Women's Health Science Program plays an integral role in promoting the development of sound policy and regulation to enhance women's health. The Science Program responds to pressing women's health issues identified from within and outside the Agency and funds research to fill the gap between basic research and regulatory decision making. The range of disciplines and research topics represented by the funded projects is diverse and includes: cancer, HIV, cardiovascular disease, osteoporosis, auto-immune disease, dietary supplements, breast implants, dioxins, post-marketing surveillance and statistical approaches to gender analysis. Funded studies encompass in vitro, animal and human studies. The results of these studies have been published in peer reviewed scientific journals, presented at scientific meetings, have provided information for the development of published regulations and guidance documents, and have contributed to outreach programs promoting women's health.

The Science Program is composed of four separate funding mechanisms that include the Intramural Research Program, the Extramural Research Program, Partnership with DHHS Centers for Excellence in Women's Health and Special Funding Initiatives. These program areas allow the Office to leverage internal and external resources to enhance the science base for women's health within the Agency. Emphasis is given to projects with the greatest potential for contributing to knowledge of women's health in a timely manner and to have a regulatory impact.

The goals of the Science Program are to:

- Address gaps in current scientific knowledge
- Encourage new directions in research
- Set new standards of excellence in women's health

From 1994-2005, OWH has awarded funds for 147 research projects totaling over $14.6 million as follows:

Intramural Research Program (n=127)	$10,267,320
Centers for Excellence (n=12)	$ 2,460,298
Extramural Contracts (n=8)	$ 1,905,187

As of March 2006, via a survey of FDA OWH funded investigators (response rate ~35%), the OWH Science Program has directly contributed to the publication of over 120 full papers in peer reviewed journals and over 125 abstracts/presentations at professional meetings.

i. **Intramural Research Program**

The Intramural Research Program supports researchers within the FDA to develop the agency's infrastructure for performing research that enhances women's health. The OWH partners with FDA research scientists to develop projects that address gaps in current knowledge or set new directions for research in studies to investigate sex differences and other women's health issues. There are 2 mechanisms for funding intramural projects, a competitive Intramural Research Program and a non-competitive small grant program (i.e., Special Funding Initiatives).

All types of research (e.g., basic science, bench, animal, human) are funded through the intramural program. Project duration is generally 1 – 3 years. The investigators must provide 2 progress reports per year (May and November). Site visits are conducted as warranted. There is 1 announcement for concept papers/proposals per year. The intramural research program utilizes a competitive peer review process to select the highest quality projects with an emphasis on projects that significantly contribute to FDA's actions on women's health. Peer reviewers include internal and external experts. This funding mechanism has been used for the longest period of time, therefore the majority of studies funded from OWH are from this funding mechanism.

Special Funding Initiatives provide the OWH with the capability to rapidly respond to immediate or recurring women's health issues. The program is designed to be extremely flexible. OWH has used the Special Funding Initiatives mechanism to co-fund topical workshops, conduct analytical surveys and host similar events targeting vital women's health issues. Items funded typically are completed in one year or less.

Intramural Selection Process (competitive)
The selection process for projects funded under the intramural program is briefly as follows:

- **Determination of priority topics** - Aligned with HHS Secretary's 500/5000 Day Plan, FDA Commissioner's Strategic Plan, FDA Critical Path Initiative, Center/Offices priorities and concerns, OWH priorities, current women's health issues and concerns, and Congressional directives and mandates. A Women's Health Advisory Council is being constructed to assist with the identification and prioritization of topic areas.
- **Announcement** – The OWH sends an FDA-wide email announcing the anticipated availability funds for scientific research and the priority research topics. The announcement requests that 1-2 page concept papers related to priority topic areas be forwarded to OWH through Center management and the OWH Coordinator. Each Center/Office has a coordinator that works directly with the OWH Science Program.
- **Review of concept papers** - Concept papers are forwarded to OWH from the Center coordinators. The Centers/Offices and OWH independently review and rank the concept papers.

- **Selection of concept papers** - OWH meets with the Center OWH Coordinators and managers to compare the ratings and rankings of the concept papers. OWH makes the final selection of concept papers to be developed into full proposals.
- **Proposal Development** – PI's of selected concept papers are notified that full proposals should be developed. When requested, representatives from OWH meet with Centers to aid in proposal development. Concurrently, OWH identifies internal and external reviewers for each proposal.
- **Proposal Review** - The goal is for each proposal to be reviewed by at least two internal (FDA – but not from the same Center) reviewers to ensure that the research is relevant to FDA's regulatory mission and by at least two external reviewers to ensure that the research is up to current scientific standards. In addition, OWH staff review all proposals. Internal and external reviewers provide written evaluations of select proposals and complete rating forms. OWH uses the internal/external evaluations for guidance in selecting proposals to be funded.
- **Awarding Grants** - OWH provides the Principle Investigators (PI) and Center management with announcements of grant awards. Transfer of funds follows OWH's receipt of a signed Letter of Agreement.
- **Grantee Orientation** - Representatives from OWH meet with each year's OWH grants awardees to review expectations and discuss common research interests.
- **Project Tracking** - Project progress is tracked throughout the life of the project. Periodic phone calls from OWH Project Officers to PIs are made to assess progress and/or resolve problems. Two interim written progress reports are required from PIs for every year of funding (May and November). OWH Project Officers review these reports and comments are sent to PIs for clarification. Site visits are conducted by OWH on an as needed annual basis. A final report is due 6 months after the completion of the project. Principle investigators are asked to provide OWH with copies of all outcome documents (manuscripts (draft and final), abstracts, posters, presentations, guidance documents, labeling, etc.) that were created as a result of OWH funding. In addition, OWH is now requesting that investigators inform the office of any other projects or initiatives that were undertaken as a result of OWH funding. This is imperative as OWH tracks the impact of its Science Program.
- **Project Completion** - OWH reviews and approves the final report. Once approved, the investigator is informed the project is closed.

Intramural Funding

One hundred and twenty-two (127) intramural projects have been funded between FY 1994-FY 2005 at a cost of approximately $10,267,320.

- Competitive Intramural Research Program
    - 102 scientific/regulatory projects funded
    - Total funding of $8,896,320
- Special Funding Initiative Program
    - 25 projects funded
    - Total funding of $1,371,000

The average cost per project for all intramural projects was $80,845 with a range of total awarded monies from $2,000 to $500,000.

Research funded by OWH since 1994:

CENTER	Dollars ($)	# of Studies
Center for Devices and Radiological Health (CDRH)	2,764,900	31
National Center for Toxicological Research (NCTR)	1,986,902	15
Center for Biologics Evaluation and Research (CBER)	1,963,220	21
Center for Drug Evaluation and Research (CDER)	1,959,698	33
Center for Food Safety and Applied Nutrition (CFSAN)	1,080,600	18
Center for Veterinary Medicine (CVM)	195,000	2
Office of Regulatory Affairs (ORA)	153,000	3
Office of International and Constituent Relations	92,000	3
Office of Women's Health	72,000	1
	10,267,320*	127

*Reflects support for research projects only. Funds given to support other Center/Office projects and initiatives are not included.

Current Intramural Projects

The FY2006 proposals are currently under review. There are currently 10 intramural projects in progress as follows:

Funded in FY 2005 (Scope - Sex and gender differences with emphasis on heart disease and obesity)

- Systems Biology Approach To Evaluate Sex Difference In Heart Of A Rat Model
  James Fuscoe, Ph.D. (NCTR)
- Sex Difference Dependent Drug-Drug Interactions Of Anti-HIV Therapeutics
  Hyojong Kwon, Ph.D. and Robert Lionberger, Ph.D. (CDER)
- Implications Of Gender-Based Differences In Cardiovascular Disease On Imaging For Treatment And Diagnosis
  Iacovos Kyprianou, Ph.D. and Kyle Myers, Ph.D. (CDRH)

Funded in FY 2004 (Scope - FDA strategic plan with emphasis on counterterrorism and patient/consumer safety)

- Gender Dimorphism In HIV Infection In Primary Macrophages And T-Lymphocytes: Kinetics Of HIV Replication And Efficacy Of Anti-Retroviral Agents
  Andrew Dayton, Ph.D. (CBER)
- Development Of Guidelines For Evaluating The Appropriateness Of Vertebroplasty Surgery For Patients With Osteoporosis
  Jove Graham, Ph.D. (CDRH)

- Do Phytoestrogens Modify The Allergic Response To Food Allergens In The Newly Validated, Highly Sensitive, In-Bred Asthmatic Rat Model?
  Dennis Hinton, Ph.D. (CFSAN)

Funded in FY 2003

- Discovery And Evaluation Of Interspecies Biomarkers To Monitor The Early Onset And The Progression Of Cardiovascular Toxicity Associated With Thiazolidinedione Compounds Used In The Treatment Of Type 2 Diabetes
  Eugene Herman, Ph.D. (CDER)
- Cardiovascular Effects Of Ultrasound Contrast Agents In Intact And Ovariectomized Female Animals
  Melvin Stratmeyer, Ph.D. (CDRH)

Funded in FY 2001

- Discovery And Evaluation Of Interspecies Biomarkers To Identify And Characterize The Cardiotoxic Effects Of Herceptin, A Novel Antibody Used In The Treatment Of Breast Cancer
  Eugene Herman, Ph.D. and Frank Sistare, Ph.D. (CDER)
- Optimization Of UV Exposure Patterns Maximizing Perceived Benefits While Minimizing Photocarcinogenic/Photo-Aging Effects
  Sharon Miller, MS and Janusz Beer, Ph.D, D.Sc. (CDRH)

ii. **Extramural Research Program**

The Extramural Research Program helps FDA scientists answer regulatory research questions that require technology, expertise, or resources not available within the Agency. OWH partners with FDA scientists to develop the research questions, contract with outside institutions and oversee the study. OWH works with the Centers to identify and prioritize topics of mutual interest for extramural research. Each contract is approximately 2-3 years in duration. The reporting requirements vary per contract (e.g., monthly, quarterly, bi-annually). At least 1 site visit is conducted per contract over the life of the contract. OWH has issued approximately 1 -2 requests for proposals per year over the last few years. The proposals are reviewed by an FDA expert panel. Extramural funding is typically for larger dollar amounts and for longer duration than intramural projects and are a relatively new funding mechanism for OWH.

To facilitate FDA's ability to conduct extramural women's health research, FDA has partnered with the Department of Health and Human Services' (DHHS) National Centers of Excellence in Women's Health (COE). The COEs were established by the DHHS Office on Women's Health in 1996. Their mandate was to create and evaluate a new model health care system uniting women's health research, medical training, clinical care, public health education, community outreach and the promotion of women in academic medicine around a common mission: to improve the health status of diverse women across the life span. The COEs provide OWH with access to highly developed research centers and leading scientists representing diverse scientific disciplines specializing in women's health.

OWH completed 7 projects in collaboration with the COEs in the areas of dietary supplements and hypertension:

- Pattern of botanical dietary supplement usage in menopausal women. Gail B. Mahady, Ph.D., University of Illinois at Chicago
- Effect of dietary soy and calcium supplementation on lipid levels, brachial artery function, biochemical markers of bone turnover, inflammatory markers of atherosclerosis and menopausal symptoms in postmenopausal women. Francine K. Welty, M.D., Ph.D., Beth Israel Deaconess Medical Center and Harvard University
- The effects of St. Johns Wort on the efficacy of oral contraception. Stephen D. Hall, Ph.D., Indiana University
- Review of herbal weight loss product experiences and adverse events. Sara L. Warber, M.D., University of Michigan
- Use and interaction of dietary supplements in the SEA Trial. Mara Vitolins, Dr.P.H., Wake Forest University
- Phytoestrogens: Drug interaction potential in women. Gail Anderson, Ph.D., University of Washington
- PK of Atenolol during Pregnancy. Mary Hebert, PharmD, University of Washington

There are currently 9 ongoing extramural contracts:

Funded in FY 2005 (Scope - Sex and gender differences)

- Cytochrome P2B6 Genotype-Phenotype and the Influence of Sex and Ethnicity (sole source contract). Erin G. Schuetz, Ph.D., St. Jude’s Research Hospital and Mei-Lin Chen, CDER
- PK and PD of Antibiotics in Pregnancy. Gloria Sarto, MD, University of Wisconsin. Note: Funded in FY 2002 (Counter-terrorism Initiative)

Funded in FY 2004 (Scope - Cardiovascular initiative)

- Reduced Efficacy of Ace Inhibition in Women. Thierry Le Jemtel, MD, Tulane University
- PK and PD of Labetolol and Hypertension in Pregnancy. Jim Fisher, PharmD, University of Illinois at Chicago
- Use and Outcomes of Coronary Stents in Women. Karen Freund, M.D., Boston University
- PK of Atenolol in Lactating Women. Mary Hebert, PharmD, University of Washington
- Transmission Attenuation Correction for Females Undergoing
- Myocardial Perfusion Imaging: Correction for Confounding Breast
- Tissue Artifact. Michelle Dew, MD, University of Arizona

Funded in FY 2003 (Scope - Pregnancy, depression and diabetes initiative)

- PK/PD of Sertraline in Pregnancy. Marlene Freeman, MD, University of Arizona
- Self Monitoring of Blood Glucose with Finger Tip vs. ALT. Caroline Apovian, MD, Boston University

iii. **Regulatory Impact of OWH Science Program**

The following table depicts several study outcomes with particular regulatory relevance:

Project	**Study Type**	**Number of participants/ records**	**Outcome**	**Regulatory Relevance**
Visualization tools for studying sex differences; Data-mining	Observational, AERS† records review	1.8 million records	Automated screening and alert system detection of potential drug interactions	Tool used for post market **surveillance** of adverse drug interactions
Quinidine Induced QTc Prolongation	Single blind, randomized (PK/PD study)	12 women, 12 men	Greater QTc response noted in women after IV quinidine	**Guidance** on evaluation of QT prolongation during drug review
Ibutilide induced QTc prolongation in women during the menstrual period	Cohort study, open label (PK/PD study)	20 women, 38 men	Increased QTc during menstrual and ovulatory phase after IV ibutilide	**Guidance** on evaluation of QT prolongation during drug review
Interaction between St. John's wort and an oral contraceptive	Cohort study, open label (PK/PD study)	12 women, premenopausal	increase in oral clearance of norethindrone; reduction in half-life of ethinyl estradiol	**Guidance** documents, **Labeling** changes for oral contraceptives
Effect of Echinacea on CYP 450±	Cohort study, open label (PK/PD study)	6 women, 6 men	Potential for drug interaction	**Labeling** changes for CYP 450± substrates
Study of silicone breast implant rupture	Cohort study	344 women	Rupture associated with age of implant, submuscular vs. subglandular implantation	**Guidance** on mechanical testing and clinical studies
Development of a universal water leak test method: Condom testing	Experimental testing	Four types of lubricated condoms, n=10 per defect, 200 controls	Characterization of defects in condoms	Adapting and establishing higher **testing standards**

†AERS: adverse event reporting system; ±CYP 450: cytochrome P450

CONCLUSIONS

FDA's Office of Women's Health (OWH) has been in existence for little over 10 years. The Office has outreach and research and development programs that cover consumer materials for FDA regulated products, the funding of research of particular relevance to FDA and women's health, and tracking how women are included in clinical studies conducted by regulated industry and submitted to FDA.

OWH is looking forward to scientific and professional interactions with the FDA Science Board. OWH would appreciate input from the Science Board on women's health issues pertinent to FDA that the Board sees as high priority or that represent a particular need. OWH's Science Program always needs external reviewers to conduct peer review of fully developed and submitted research proposals. OWH would welcome the involvement of FDA Science Board members. The expertise of the Science Board could contribute substantially to the OWH Science Program and further the scientific gains of OWH funded research.

Should you have any further questions regarding OWH, please feel free to contact me.

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